

## PCT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
 US Department of Commerce  
 United States Patent and Trademark  
 Office, PCT  
 2011 South Clark Place Room  
 CP2/5C24  
 Arlington, VA 22202  
 ETATS-UNIS D'AMERIQUE  
 in its capacity as elected Office

<b>Date of mailing (day/month/year)</b> 30 October 2000 (30.10.00)	
<b>International application No.</b> PCT/JP00/01070	<b>Applicant's or agent's file reference</b> 1192
<b>International filing date (day/month/year)</b> 24 February 2000 (24.02.00)	<b>Priority date (day/month/year)</b> 25 February 1999 (25.02.99)
<b>Applicant</b> NARIMATSU, Hisashi et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

21 September 2000 (21.09.00)

☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<b>The International Bureau of WIPO</b> 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No.: (41-22) 740.14.35	<b>Authorized officer</b>  R. Forax  Telephone No.: (41-22) 338.83.38
----------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------

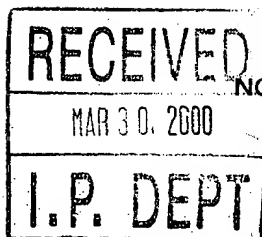
## PCT COOPERATION TRE

PCT

From the INTERNATIONAL BUREAU

To:

KYOWA HAKKO KOGYO CO., LTD.  
6-1, Ohtemachi 1-chome  
Chiyoda-ku  
Tokyo 100-8185  
JAPON

NOTIFICATION OF RECEIPT OF  
RECORD COPY

(PCT Rule 24.2(a))

WPAJD

Date of mailing (day/month/year) 15 March 2000 (15.03.00)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 1192	International application No. PCT/JP00/01070

The applicant is hereby notified that the International Bureau has received the record copy of the international application as detailed below.

Name(s) of the applicant(s) and State(s) for which they are applicants:

KYOWA HAKKO KOGYO CO., LTD. (for all designated States except US)  
NARIMATSU, Hisashi et al (for US)

International filing date : 24 February 2000 (24.02.00)

Priority date(s) claimed : 25 February 1999 (25.02.99)

Date of receipt of the record copy  
by the International Bureau : 10 March 2000 (10.03.00)

List of designated Offices :

AP : GH,GM,KE,LS,MW,SD,SL,SZ,TZ,UG,ZW  
EA : AM,AZ,BY,KG,KZ,MD,RU,TJ,TM  
EP : AT,BE,CH,CY,DE,DK,ES,FI,FR,GB,GR,IE,IT,LU,MC,NL,PT,SE  
OA : BF,BJ,CF,CG,CI,CM,GA,GN,GW,ML,MR,NE,SN,TD,TG  
National : AE,AL,AM,AT,AU,AZ,BA,BB,BG,BR,BY,CA,CH,CN,CR,CU,CZ,DE,DK,DM,EE,ES,FI,GB,  
GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KR,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,  
MW,MX,NO,NZ,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,US,UZ,VN,YU,ZA,ZW

## ATTENTION

The applicant should carefully check the data appearing in this Notification. In case of any discrepancy between these data and the indications in the international application, the applicant should immediately inform the International Bureau.

In addition, the applicant's attention is drawn to the information contained in the Annex, relating to:

☒ time limits for entry into the national phase

☒ confirmation of precautionary designations

☒ requirements regarding priority documents

A copy of this Notification is being sent to the receiving Office and to the International Searching Authority.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer:  Y. KUWAHARA
Facsimile No. (41-22) 740.14.35	Telephone No. (41-22) 338.83.38

## INFORMATION ON TIME LIMITS FOR ENTERING THE NATIONAL PHASE

The applicant is reminded that the "national phase" must be entered before each of the designated Offices indicated in the Notification of Receipt of Record Copy (Form PCT/IB/301) by paying national fees and furnishing translations, as prescribed by the applicable national laws.

The time limit for performing these procedural acts is **20 MONTHS** from the priority date or, for those designated States which the applicant elects in a demand for international preliminary examination or in a later election, **30 MONTHS** from the priority date, provided that the election is made before the expiration of 19 months from the priority date. Some designated (or elected) Offices have fixed time limits which expire even later than 20 or 30 months from the priority date. In other Offices an extension of time or grace period, in some cases upon payment of an additional fee, is available.

In addition to these procedural acts, the applicant may also have to comply with other special requirements applicable in certain Offices. **It is the applicant's responsibility** to ensure that the necessary steps to enter the national phase are taken in a timely fashion. Most designated Offices do not issue reminders to applicants in connection with the entry into the national phase.

**For detailed information about the procedural acts to be performed to enter the national phase before each designated Office, the applicable time limits and possible extensions of time or grace periods, and any other requirements, see the relevant Chapters of Volume II of the PCT Applicant's Guide. Information about the requirements for filing a demand for international preliminary examination is set out in Chapter IX of Volume I of the PCT Applicant's Guide.**

GR and ES became bound by PCT Chapter II on 7 September 1996 and 6 September 1997, respectively, and may, therefore, be elected in a demand or a later election filed on or after 7 September 1996 and 6 September 1997, respectively, regardless of the filing date of the international application. (See second paragraph above.)

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

## CONFIRMATION OF PRECAUTIONARY DESIGNATIONS

This notification lists only specific designations made under Rule 4.9(a) in the request. It is important to check that these designations are correct. Errors in designations can be corrected where precautionary designations have been made under Rule 4.9(b). The applicant is hereby reminded that any precautionary designations may be confirmed according to Rule 4.9(c) before the expiration of 15 months from the priority date. If it is not confirmed, it will automatically be regarded as withdrawn by the applicant. There will be no reminder and no invitation. Confirmation of a designation consists of the filing of a notice specifying the designated State concerned (with an indication of the kind of protection or treatment desired) and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.

## REQUIREMENTS REGARDING PRIORITY DOCUMENTS

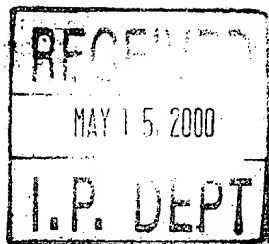
For applicants who have not yet complied with the requirements regarding priority documents, the following is recalled.

Where the priority of an earlier national, regional or international application is claimed, the applicant must submit a copy of the said earlier application, certified by the authority with which it was filed ("the priority document") to the receiving Office (which will transmit it to the International Bureau) or directly to the International Bureau, before the expiration of 16 months from the priority date, provided that any such priority document may still be submitted to the International Bureau before that date of international publication of the international application, in which case that document will be considered to have been received by the International Bureau on the last day of the 16-month time limit (Rule 17.1(a)).

Where the priority document is issued by the receiving Office, the applicant may, instead of submitting the priority document, request the receiving Office to prepare and transmit the priority document to the International Bureau. Such request must be made before the expiration of the 16-month time limit and may be subjected by the receiving Office to the payment of a fee (Rule 17.1(b)).

If the priority document concerned is not submitted to the International Bureau or if the request to the receiving Office to prepare and transmit the priority document has not been made (and the corresponding fee, if any, paid) within the applicable time limit indicated under the preceding paragraphs, any designated State may disregard the priority claim, provided that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity to furnish the priority document within a time limit which is reasonable under the circumstances.

Where several priorities are claimed, the priority date to be considered for the purposes of computing the 16-month time limit is the filing date of the earliest application whose priority is claimed.



WPBJD

## PCT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

To:

KYOWA HAKKO KOGYO CO., LTD.  
6-1, Ohtemachi 1-chome  
Chiyoda-ku  
Tokyo 100-8185  
JAPON

NOTIFICATION CONCERNING  
SUBMISSION OR TRANSMITTAL  
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

Date of mailing (day/month/year) 02 May 2000 (02.05.00)	
Applicant's or agent's file reference 1192	<b>IMPORTANT NOTIFICATION</b>
International application No. PCT/JP00/01070	International filing date (day/month/year) 24 February 2000 (24.02.00)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 25 February 1999 (25.02.99)
Applicant KYOWA HAKKO KOGYO CO., LTD. et al	

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
3. An asterisk(\*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
4. The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
25 Febr 1999 (25.02.99)	11/47571	JP	14 Apr 2000 (14.04.00)

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

Somsak Thiphrakesone

Telephone No. (41-22) 338.83.38

# PCT COOPERATION TRE

PCT

## NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

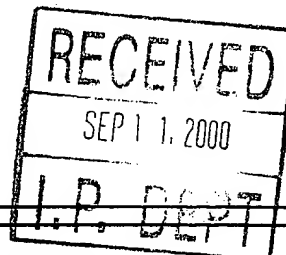
(PCT Rule 47.1(c), first sentence)

From the INTERNATIONAL BUREAU

To:

KYOWA HAKKO KOGYO CO., LTD.  
6-1, Ohtemachi 1-chome  
Chiyoda-ku  
Tokyo 100-8185  
JAPON

WPCJD  
PLPJD



Date of mailing (day/month/year) 31 August 2000 (31.08.00)		IMPORTANT NOTICE	
Applicant's or agent's file reference 1192			
International application No. PCT/JP00/01070	International filing date (day/month/year) 24 February 2000 (24.02.00)	Priority date (day/month/year) 25 February 1999 (25.02.99)	
Applicant KYOWA HAKKO KOGYO CO., LTD. et al			

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:  
AU, KR, US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:  
AE, AL, AM, AP, AT, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EA, EE, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, OA, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW  
The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).
3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 31 August 2000 (31.08.00) under No. WO 00/50608

### REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

### REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer J. Zahra
Facsimile No. (41-22) 740.14.35	Telephone No. (41-22) 338.83.38

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1192	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP00/01070	International filing date ( <i>day/month/year</i> ) 24 February 2000 (24.02.00)	Priority date ( <i>day/month/year</i> ) 25 February 1999 (25.02.99)
International Patent Classification (IPC) or national classification and IPC C12N 15/54, C12P 21/02, C12N 9/10, 1/21, 5/14, 5/16, C12Q 1/68, C12N 15/63, A01K 67/027, G01N 33/15, 33/50, 33/574, A01H 5/00		
Applicant KYOWA HAKKO KOGYO CO., LTD.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 21 September 2000 (21.09.00)	Date of completion of this report 13 February 2001 (13.02.2001)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP00/01070

## I. Basis of the report

1. With regard to the **elements** of the international application:\*

- ☐ the international application as originally filed
- ☒ the description:  
pages \_\_\_\_\_ 1-80 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the claims:  
pages \_\_\_\_\_ 1-45 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_ 46-47 \_\_\_\_\_, filed with the letter of \_\_\_\_\_ 02 February 2001 (02.02.2001)
- ☒ the drawings:  
pages \_\_\_\_\_ 1-6 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the sequence listing part of the description:  
pages \_\_\_\_\_ 1-23 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	1-47	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-47	NO
Industrial applicability (IA)	Claims	1-47	YES
	Claims		NO

**2. Citations and explanations**

Document 1: D. Zhou et al., "A  $\beta$ -1,3-N-acetyl-glucosaminyltransferase with poly-N-acetyllactosamine synthase activity is structurally related to  $\beta$ -1,3-galactosyltransferases", Proc. Nat. Acad. Sci. USA (Jan. 1999), Vol. 96, No. 2, pp. 406-411

Document 2: M. Amado et al, "A family of human  $\beta$ -3-galactosyltransferases", J. Biol. Chem. (1998), Vol. 273, No. 21, pp. 12770-12778

Claims 1-39 46 and 47

Document 1 discloses partial amino acid sequences of high homology in murine  $\beta$ -1,3-N-galactosyltransferase ( $\beta$ 3GalT) I, II, III and IV having  $\beta$ 3GalT activity (Document 1, page 409, Fig. 2).

Document 2 discloses partial amino acid sequences of high homology in human  $\beta$ 3GalT-I, II, III and IV (Document. 2, page 12772, Fig. 2).

A person skilled in the art could easily conceive of cloning other enzymes having  $\beta$ 3GalT activity from a cDNA library, using the sequences of high homology in the  $\beta$ 3GalTs disclosed in Documents 1 and 2.

Incorporation of cloned DNA into a suitable vector and transformation of a host, production of a polypeptide



by culturing transformants thus obtained, use of the resulting polypeptide to obtain a reaction product by reaction of a substrate, production of an antibody which reacts with the polypeptide, detection of the polypeptide, screening of compounds which modify the activity of the polypeptide, assaying the quantity expressed by means of hybridization using a DNA fragment, and related procedures, are processes conventionally available to a person skilled in the art once DNA has been prepared.

Therefore, the inventions described in Claims 1-39, 46 and 47 could easily be invented by a person skilled in the art with reference to disclosures in Document 1 and/or 2.

#### Claims 40-45

A person skilled in the art could determine a promoter sequence by screening a genome library using DNA obtained by the methods mentioned above by using known techniques.

Use of the resulting promoter DNA to screen for compounds which alter the replicating activity of the promoter is also a routine option available to a person skilled in the art.

Therefore, the inventions described in Claims 40-45 could also easily be invented by a person skilled in the art with references to disclosures in Document 1 and/or 2.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP00/01070

## VI. Certain documents cited

### 1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
JP,11-56373,A [E,X]	02 March 1999 (02.03.1999)	27 August 1997 (27.08.1997)	

### 2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)

特 許 協 力 条 約

P C T

国際予備審査報告

(法第12条、法施行規則第56条)  
(PCT36条及びPCT規則70)

REC'D 02 MAR 2001

WIPO PCT

出願人又は代理人 の書類記号 1192	今後の手続きについては、国際予備審査報告の送付通知(様式PCT/ IPEA/416)を参照すること。	
国際出願番号 PCT/JPO0/01070	国際出願日 (日.月.年) 24.02.00	優先日 (日.月.年) 25.02.99
国際特許分類(IPC) Int.Cl <sup>7</sup> C12N15/54, C12P21/02, C12N9/10, C12N1/21, C12N5/14, C12N5/16, C12Q1/68, C12N15/63, A01K67/027, G01N33/15, G01N33/50, G01N33/574, A01H5/00		
出願人(氏名又は名称) 協和醗酵工業株式会社		

- 国際予備審査機関が作成したこの国際予備審査報告を法施行規則第57条(PCT36条)の規定に従い送付する。
- この国際予備審査報告は、この表紙を含めて全部で 5 ページからなる。  
☒ この国際予備審査報告には、附属書類、つまり補正されて、この報告の基礎とされた及び/又はこの国際予備審査機関に対してした訂正を含む明細書、請求の範囲及び/又は図面も添付されている。  
(PCT規則70.16及びPCT実施細則第607号参照)  
この附属書類は、全部で 2 ページである。
- この国際予備審査報告は、次の内容を含む。
  - ☒ 国際予備審査報告の基礎
  - ☐ 優先権
  - ☐ 新規性、進歩性又は産業上の利用可能性についての国際予備審査報告の不作成
  - ☐ 発明の単一性の欠如
  - ☒ PCT35条(2)に規定する新規性、進歩性又は産業上の利用可能性についての見解、それを裏付けるための文献及び説明
  - ☒ ある種の引用文献
  - ☐ 国際出願の不備
  - ☐ 国際出願に対する意見

国際予備審査の請求書を受理した日 21.09.00	国際予備審査報告を作成した日 13.02.01		
名称及びあて先 日本国特許庁(IPEA/JP) 郵便番号100-8915 東京都千代田区霞が関三丁目4番3号	特許庁審査官(権限のある職員) 六笠 紀子 印	4B	9735
電話番号 03-3581-1101 内線 3448			

様式PCT/IPEA/409(表紙)(1998年7月)

## I. 国際予備審査報告の基礎

1. この国際予備審査報告は下記の出願書類に基づいて作成された。(法第6条(PCT14条)の規定に基づく命令に  
 応答するために提出された差し替え用紙は、この報告書において「出願時」とし、本報告書には添付しない。  
 PCT規則70.16, 70.17)

☐ 出願時の国際出願書類

☒ 明細書 第 1-80 ページ、 出願時に提出されたもの  
 明細書 第 \_\_\_\_\_ ページ、 国際予備審査の請求書と共に提出されたもの  
 明細書 第 \_\_\_\_\_ ページ、 \_\_\_\_\_ 付の書簡と共に提出されたもの

☒ 請求の範囲 第 1-45 項、 出願時に提出されたもの  
 請求の範囲 第 \_\_\_\_\_ 項、 PCT19条の規定に基づき補正されたもの  
 請求の範囲 第 \_\_\_\_\_ 項、 国際予備審査の請求書と共に提出されたもの  
 請求の範囲 第 46, 47 項、 02.02.01 付の書簡と共に提出されたもの

☒ 図面 第 1-6 ページ/図、 出願時に提出されたもの  
 図面 第 \_\_\_\_\_ ページ/図、 国際予備審査の請求書と共に提出されたもの  
 図面 第 \_\_\_\_\_ ページ/図、 \_\_\_\_\_ 付の書簡と共に提出されたもの

☒ 明細書の配列表の部分 第 1-23 ページ、 出願時に提出されたもの  
 明細書の配列表の部分 第 \_\_\_\_\_ ページ、 国際予備審査の請求書と共に提出されたもの  
 明細書の配列表の部分 第 \_\_\_\_\_ ページ、 \_\_\_\_\_ 付の書簡と共に提出されたもの

2. 上記の出願書類の言語は、下記に示す場合を除くほか、この国際出願の言語である。

上記の書類は、下記の言語である \_\_\_\_\_ 語である。

- ☐ 国際調査のために提出されたPCT規則23.1(b)にいう翻訳文の言語  
☐ PCT規則48.3(b)にいう国際公開の言語  
☐ 国際予備審査のために提出されたPCT規則55.2または55.3にいう翻訳文の言語

3. この国際出願は、ヌクレオチド又はアミノ酸配列を含んでおり、次の配列表に基づき国際予備審査報告を行った。

- ☐ この国際出願に含まれる書面による配列表  
☒ この国際出願と共に提出されたフレキシブルディスクによる配列表  
☐ 出願後に、この国際予備審査（または調査）機関に提出された書面による配列表  
☐ 出願後に、この国際予備審査（または調査）機関に提出されたフレキシブルディスクによる配列表  
☐ 出願後に提出した書面による配列表が出願時における国際出願の開示の範囲を超える事項を含まない旨の陳述書の提出があった  
☒ 書面による配列表に記載した配列とフレキシブルディスクによる配列表に記載した配列が同一である旨の陳述書の提出があった。

4. 補正により、下記の書類が削除された。

☐ 明細書 第 \_\_\_\_\_ ページ  
☐ 請求の範囲 第 \_\_\_\_\_ 項  
☐ 図面 図面の第 \_\_\_\_\_ ページ/図

5. ☐ この国際予備審査報告は、補充欄に示したように、補正が出願時における開示の範囲を越えてされたものと認められるので、その補正がされなかったものとして作成した。(PCT規則70.2(c) この補正を含む差し替え用紙は上記1.における判断の際に考慮しなければならず、本報告に添付する。)

## V. 新規性、進歩性又は産業上の利用可能性についての法第12条(PCT35条(2))に定める見解、それを裏付ける文献及び説明

## 1. 見解

新規性(N)

請求の範囲

1-47

有

請求の範囲

無

進歩性(IS)

請求の範囲

有

請求の範囲

1-47

無

産業上の利用可能性(IA)

請求の範囲

1-47

有

請求の範囲

無

## 2. 文献及び説明(PCT規則70.7)

引用文献1: ZHOU, D. et al, "A  $\beta$ -1,3-N-acetylglucosaminyltransferase with poly-N-acetyllactosamine synthase activity is structurally related to  $\beta$ -1,3-galactosyltransferases", Proc. Natl. Acad. Sci. USA., (Jan., 1999) Vol. 96, No. 2 p. 406-411

引用文献2: AMADO, M. et al, "A family of human  $\beta$ 3-galactosyltransferases", J. Biol. Chem., (1998) Vol. 273, No. 21, p. 12770-12778

請求の範囲 1-39、46、47

引用文献1には、 $\beta$ -1, 3-N-ガラクトース転移酵素( $\beta$ 3GalT)活性を有するマウスの $\beta$ 3GalT-I, II, III及びIVのアミノ酸配列のホモロジーの高い部分が記載されている(引用文献1第409頁Fig. 2)。

引用文献2には、ヒトの $\beta$ 3GalT-I, II, III及びIVのアミノ酸配列のホモロジーの高い部分が記載されている(引用文献2第12772頁Fig. 2)。

ここで、引用文献1や2に記載された $\beta$ 3GalTのホモロジーの高い部分の配列をもとに $\beta$ 3GalT活性をもつ他の酵素をcDNAライブラリーからクローニングすることは当業者が容易に想到し得たものと認める。

また、クローニングされたDNAを適当なベクターに組み込んで宿主を形質転換すること、このようにして得られた形質転換体を培養してポリペプチドを製造すること、製造されたポリペプチドを用いて基質を反応させ反応産物を得ること、ポリペプチドに反応する抗体を作製し、ポリペプチドを検出すること、ポリペプチドの有する活性を変動させる化合物のスクリーニングを行うこと、及び、DNA断片を用いてハイブリダイゼーション法により発現量を測定すること等はDNAが調製されれば当業者が通常なし得た一連の工程である。

従って、請求の範囲1乃至39、46及び47に係る発明は引用文献1や2の記載に基づいて当業者が容易になし得たものと認める。

## VI. ある種の引用文献

## 1. ある種の公表された文書 (PCT規則70.10)

出願番号 特許番号	公知日 (日. 月. 年)	出願日 (日. 月. 年)	優先日 (有効な優先権の主張) (日. 月. 年)
JP, 11-56373, A 「E, X」	02. 03. 99	27. 08. 97	

## 2. 書面による開示以外の開示 (PCT規則70.9)

書面による開示以外の開示の種類	書面による開示以外の開示の日付 (日. 月. 年)	書面による開示以外の開示に言及している 書面の日付 (日. 月. 年)
-----------------	------------------------------	----------------------------------------

補充欄 (いずれかの欄の大きさが足りない場合に使用すること)

## 第 V 欄の続き

## 請求の範囲 40-45

上記の方法で、得られたDNAをもとにゲノムライブラリーをスクリーニングしてプロモーター配列を決定することは当業者が周知の技術を用いてなし得たことである。

そして、このようにして得られたプロモーターDNAを用いてプロモーターの転写活性の変動をさせる化合物のスクリーニングをすることは当業者が必要に応じて適宜なし得たものと認める。

従って、請求の範囲40乃至45に係る発明は引用文献1や2の記載に基づいて当業者が容易になし得たものと認める。

ーニング法。

39. 請求項 1 ～ 4 のいずれか 1 項に記載のポリペプチドを発現する細胞と被験試料とを接触させ、請求項 3 2 記載の抗体を用い、該ポリペプチド含量を測定することを特徴とする、該ポリペプチドをコードする遺伝子の発現を変動させる化合物のスクリーニング法。

40. 請求項 1 ～ 4 のいずれか 1 項に記載のポリペプチドをコードする遺伝子の転写を司るプロモーター DNA。

41. プロモーター DNA が、小腸細胞、大腸細胞、膵臓細胞、胃細胞、大腸癌細胞、膵癌細胞および胃癌細胞からなる群より選ばれる細胞で機能しているプロモーターである、請求項 4 0 記載のプロモーター DNA。

42. プロモーター DNA が、ヒトまたはマウス由来のプロモーター DNA である、請求項 4 0 または 4 1 記載のプロモーター DNA。

43. プロモーター DNA が、配列番号 3 で表される塩基配列の 1 ～ 5 0 0 0 番目の塩基配列中の連続する 5 0 ～ 5 0 0 0 b p の DNA 配列を有する、請求項 4 0 ～ 4 2 のいずれか 1 項に記載のプロモーター DNA。

44. 請求項 4 0 ～ 4 3 のいずれか 1 項に記載のプロモーター DNA および該プロモーター DNA の下流に連結させたレポーター遺伝子を含有するプラスミドを用いて動物細胞を形質転換し、該形質転換体と被験試料とを接触させ、該レポーター遺伝子の翻訳産物の含量を測定することを特徴とする、該プロモーターによる転写の効率を変動させる化合物のスクリーニング法。

45. レポーター遺伝子が、クロラムフェニコール・アセチルトランスフェラーゼ遺伝子、 $\beta$ -グルクロニダーゼ遺伝子、 $\beta$ -ガラクトシダーゼ遺伝子、 $\beta$ -ラクタマーゼ遺伝子、ルシフェラーゼ遺伝子、エクオリン遺伝子およびグリーン・フルオレッセント・プロテイン遺伝子より選ばれる遺伝子である、請求項 4 4 記載のスクリーニング法。

46(補正後). 請求項 1 ～ 4 のいずれか 1 項に記載のポリペプチドをコードする DNA を欠損または変異させたノックアウト非ヒト動物。



47(補正後). ノックアウト非ヒト動物がマウスである、請求項 4 6 記載  
のノックアウト非ヒト動物。

# PCT

## REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

097914152

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference  
(if desired) (12 characters maximum)

1192

**Box No. I TITLE OF INVENTION**  
NOVEL POLYPEPTIDES

**Box No. II APPLICANT**

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

KYOWA HAKKO KOGYO CO., LTD.

6-1, Ohtemachi 1-chome, Chiyoda-ku, Tokyo 100-8185  
Japan

☐ This person is also inventor.

Telephone No. 03-3282-0036

Facsimile No. 03-3282-1527

Teleprinter No.

State (that is, country) of nationality: JP

State (that is, country) of residence: JP

This person is applicant for the purposes of:

☐ all designated States

☒ all designated States except the United States of America

☐ the United States of America only

☐ the States indicated in the Supplemental Box

**Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)**

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

Hisashi Narimatsu

5-1082-1, Mukohara, Higashiyamato-shi, Tokyo  
207-0013 Japan

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality: JP

State (that is, country) of residence: JP

This person is applicant for the purposes of:

☐ all designated States

☐ all designated States except the United States of America

☒ the United States of America only

☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

**Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE**

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:

☐ agent

☐ common representative

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

Telephone No.

Facsimile No.

Teleprinter No.

☐ Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III <b>FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)</b>	
<i>If none of the following sub-boxes is used, this sheet should not be included in the request.</i>	
<p><small>Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</small></p> <p>Soichiro Isshiki</p> <p>1-30-2-101, Chuo, Nakano-ku, Tokyo 164-0011 Japan</p>	<p>This person is:</p> <p><input type="checkbox"/> applicant only</p> <p><input checked="" type="checkbox"/> applicant and inventor</p> <p><input type="checkbox"/> inventor only (If this check-box is marked, do not fill in below.)</p>
State (that is, country) of nationality:    JP	State (that is, country) of residence:    JP
<p>This person is applicant for the purposes of:    <input type="checkbox"/> all designated States    <input type="checkbox"/> all designated States except the United States of America    <input checked="" type="checkbox"/> the United States of America only    <input type="checkbox"/> the States indicated in the Supplemental Box</p>	
<p><small>Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</small></p> <p>Akira Togayachi</p> <p>1-11-42, Shimosato, Higashikurume-shi, Tokyo 203-0043 Japan</p>	<p>This person is:</p> <p><input type="checkbox"/> applicant only</p> <p><input checked="" type="checkbox"/> applicant and inventor</p> <p><input type="checkbox"/> inventor only (If this check-box is marked, do not fill in below.)</p>
State (that is, country) of nationality:    JP	State (that is, country) of residence:    JP
<p>This person is applicant for the purposes of:    <input type="checkbox"/> all designated States    <input type="checkbox"/> all designated States except the United States of America    <input checked="" type="checkbox"/> the United States of America only    <input type="checkbox"/> the States indicated in the Supplemental Box</p>	
<p><small>Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</small></p> <p>Katsutoshi Sasaki</p> <p>c/o Tokyo Research Laboratories KYOWA HAKKO KOGYO CO., LTD. 6-6, Asahi-machi 3-chome, Machida-shi, Tokyo 194-8533 Japan</p>	<p>This person is:</p> <p><input type="checkbox"/> applicant only</p> <p><input checked="" type="checkbox"/> applicant and inventor</p> <p><input type="checkbox"/> inventor only (If this check-box is marked, do not fill in below.)</p>
State (that is, country) of nationality:    JP	State (that is, country) of residence:    JP
<p>This person is applicant for the purposes of:    <input type="checkbox"/> all designated States    <input type="checkbox"/> all designated States except the United States of America    <input checked="" type="checkbox"/> the United States of America only    <input type="checkbox"/> the States indicated in the Supplemental Box</p>	
<p><small>Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</small></p>	<p>This person is:</p> <p><input type="checkbox"/> applicant only</p> <p><input type="checkbox"/> applicant and inventor</p> <p><input type="checkbox"/> inventor only (If this check-box is marked, do not fill in below.)</p>
State (that is, country) of nationality:	State (that is, country) of residence:
<p>This person is applicant for the purposes of:    <input type="checkbox"/> all designated States    <input type="checkbox"/> all designated States except the United States of America    <input type="checkbox"/> the United States of America only    <input type="checkbox"/> the States indicated in the Supplemental Box</p>	
<p><input type="checkbox"/> Further applicants and/or (further) inventors are indicated on another continuation sheet.</p>	

**Box No. V DESIGNATION OF STATES**

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be marked):

**Regional Patent**

- ☒ **AP ARIPO Patent:** GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SL Sierra Leone, SZ Swaziland, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ **EA Eurasian Patent:** AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ **EP European Patent:** AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ **OA OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line) .....

National Patent (if other kind of protection or treatment desired, specify on dotted line):

- |                                                                                    |                                                                                         |
|------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> <b>AE</b> United Arab Emirates                 | <input checked="" type="checkbox"/> <b>LR</b> Liberia                                   |
| <input checked="" type="checkbox"/> <b>AL</b> Albania                              | <input checked="" type="checkbox"/> <b>LS</b> Lesotho                                   |
| <input checked="" type="checkbox"/> <b>AM</b> Armenia                              | <input checked="" type="checkbox"/> <b>LT</b> Lithuania                                 |
| <input checked="" type="checkbox"/> <b>AT</b> Austria                              | <input checked="" type="checkbox"/> <b>LU</b> Luxembourg                                |
| <input checked="" type="checkbox"/> <b>AU</b> Australia                            | <input checked="" type="checkbox"/> <b>LV</b> Latvia                                    |
| <input checked="" type="checkbox"/> <b>AZ</b> Azerbaijan                           | <input checked="" type="checkbox"/> <b>MD</b> Republic of Moldova                       |
| <input checked="" type="checkbox"/> <b>BA</b> Bosnia and Herzegovina               | <input checked="" type="checkbox"/> <b>MG</b> Madagascar                                |
| <input checked="" type="checkbox"/> <b>BB</b> Barbados                             | <input checked="" type="checkbox"/> <b>MK</b> The former Yugoslav Republic of Macedonia |
| <input checked="" type="checkbox"/> <b>BG</b> Bulgaria                             | <input checked="" type="checkbox"/> <b>MN</b> Mongolia                                  |
| <input checked="" type="checkbox"/> <b>BR</b> Brazil                               | <input checked="" type="checkbox"/> <b>MW</b> Malawi                                    |
| <input checked="" type="checkbox"/> <b>BY</b> Belarus                              | <input checked="" type="checkbox"/> <b>MX</b> Mexico                                    |
| <input checked="" type="checkbox"/> <b>CA</b> Canada                               | <input checked="" type="checkbox"/> <b>NO</b> Norway                                    |
| <input checked="" type="checkbox"/> <b>CH and LI</b> Switzerland and Liechtenstein | <input checked="" type="checkbox"/> <b>NZ</b> New Zealand                               |
| <input checked="" type="checkbox"/> <b>CN</b> China                                | <input checked="" type="checkbox"/> <b>PL</b> Poland                                    |
| <input checked="" type="checkbox"/> <b>CU</b> Cuba                                 | <input checked="" type="checkbox"/> <b>PT</b> Portugal                                  |
| <input checked="" type="checkbox"/> <b>CZ</b> Czech Republic                       | <input checked="" type="checkbox"/> <b>RO</b> Romania                                   |
| <input checked="" type="checkbox"/> <b>DE</b> Germany                              | <input checked="" type="checkbox"/> <b>RU</b> Russian Federation                        |
| <input checked="" type="checkbox"/> <b>DK</b> Denmark                              | <input checked="" type="checkbox"/> <b>SD</b> Sudan                                     |
| <input checked="" type="checkbox"/> <b>EE</b> Estonia                              | <input checked="" type="checkbox"/> <b>SE</b> Sweden                                    |
| <input checked="" type="checkbox"/> <b>ES</b> Spain                                | <input checked="" type="checkbox"/> <b>SG</b> Singapore                                 |
| <input checked="" type="checkbox"/> <b>FI</b> Finland                              | <input checked="" type="checkbox"/> <b>SI</b> Slovenia                                  |
| <input checked="" type="checkbox"/> <b>GB</b> United Kingdom                       | <input checked="" type="checkbox"/> <b>SK</b> Slovakia                                  |
| <input checked="" type="checkbox"/> <b>GD</b> Grenada                              | <input checked="" type="checkbox"/> <b>SL</b> Sierra Leone                              |
| <input checked="" type="checkbox"/> <b>GE</b> Georgia                              | <input checked="" type="checkbox"/> <b>TJ</b> Tajikistan                                |
| <input checked="" type="checkbox"/> <b>GH</b> Ghana                                | <input checked="" type="checkbox"/> <b>TM</b> Turkmenistan                              |
| <input checked="" type="checkbox"/> <b>GM</b> Gambia                               | <input checked="" type="checkbox"/> <b>TR</b> Turkey                                    |
| <input checked="" type="checkbox"/> <b>HR</b> Croatia                              | <input checked="" type="checkbox"/> <b>TT</b> Trinidad and Tobago                       |
| <input checked="" type="checkbox"/> <b>HU</b> Hungary                              | <input checked="" type="checkbox"/> <b>UA</b> Ukraine                                   |
| <input checked="" type="checkbox"/> <b>ID</b> Indonesia                            | <input checked="" type="checkbox"/> <b>UG</b> Uganda                                    |
| <input checked="" type="checkbox"/> <b>IL</b> Israel                               | <input checked="" type="checkbox"/> <b>US</b> United States of America                  |
| <input checked="" type="checkbox"/> <b>IN</b> India                                | <input checked="" type="checkbox"/> <b>UZ</b> Uzbekistan                                |
| <input checked="" type="checkbox"/> <b>IS</b> Iceland                              | <input checked="" type="checkbox"/> <b>VN</b> Viet Nam                                  |
| <input checked="" type="checkbox"/> <b>JP</b> Japan                                | <input checked="" type="checkbox"/> <b>YU</b> Yugoslavia                                |
| <input checked="" type="checkbox"/> <b>KE</b> Kenya                                | <input checked="" type="checkbox"/> <b>ZA</b> South Africa                              |
| <input checked="" type="checkbox"/> <b>KG</b> Kyrgyzstan                           | <input checked="" type="checkbox"/> <b>ZW</b> Zimbabwe                                  |
| <input type="checkbox"/> <b>KP</b> Democratic People's Republic of Korea           |                                                                                         |
| <input checked="" type="checkbox"/> <b>KR</b> Republic of Korea                    |                                                                                         |
| <input checked="" type="checkbox"/> <b>KZ</b> Kazakhstan                           |                                                                                         |
| <input checked="" type="checkbox"/> <b>LC</b> Saint Lucia                          |                                                                                         |
| <input checked="" type="checkbox"/> <b>LK</b> Sri Lanka                            |                                                                                         |

Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet:

- |                                                          |                                                        |
|----------------------------------------------------------|--------------------------------------------------------|
| <input checked="" type="checkbox"/> <b>CR</b> Costa Rica | <input checked="" type="checkbox"/> <b>TZ</b> Tanzania |
| <input checked="" type="checkbox"/> <b>DM</b> Dominica   | <input checked="" type="checkbox"/> <b>MA</b> Morocco  |

**Precautionary Designation Statement:** In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)

<b>Box No. VI PRIORITY CLAIM</b>		<input type="checkbox"/> Further priority claims are indicated in the Supplemental Box.		
Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:		
		national application: country	regional application:* regional Office	international application: receiving Office
item (1) 25/02/99	47571/99	JP		
item (2)				
item (3)				
<input checked="" type="checkbox"/> The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office) identified above as item(s): (1)				
<p>* Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.</p>				
<b>Box No. VII INTERNATIONAL SEARCHING AUTHORITY</b>				
Choice of International Searching Authority (ISA) (if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):		Request to use results of earlier search; reference to that search (if an earlier search has been carried out by or requested from the International Searching Authority):		
ISA / JP		Date (day/month/year)	Number	Country (or regional Office)
<b>Box No. VIII CHECK LIST; LANGUAGE OF FILING</b>				
This international application contains the following number of sheets:		This international application is accompanied by the item(s) marked below:		
request : 4		1. <input checked="" type="checkbox"/> fee calculation sheet		
description (excluding sequence listing part) : 80		2. <input type="checkbox"/> separate signed power of attorney		
claims : 8		3. <input type="checkbox"/> copy of general power of attorney; reference number, if any:		
abstract : 1		4. <input type="checkbox"/> statement explaining lack of signature		
drawings : 6		5. <input type="checkbox"/> priority document(s) identified in Box No. VI as item(s):		
sequence listing part of description : 23		6. <input type="checkbox"/> translation of international application into (language):		
Total number of sheets : 122		7. <input checked="" type="checkbox"/> separate indications concerning deposited microorganism or other biological material		
		8. <input checked="" type="checkbox"/> nucleotide and/or amino acid sequence listing in computer readable form		
		9. <input checked="" type="checkbox"/> other (specify): written statement and document providing information about PD record format, etc.		
Figure of the drawings which should accompany the abstract:		Language of filing of the international application: JP		
<b>Box No. IX SIGNATURE OF APPLICANT OR AGENT</b>				
Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).				
<div style="display: flex; justify-content: space-between;"> <div> Hisashi Narimatsu   KYOWA HAKKO KOGYO CO., LTD. </div> <div> Akira Togayachi   Soichiro Isshiki   Katsutoshi Sasaki </div> </div>				

For receiving Office use only	
1. Date of actual receipt of the purported international application:	2. Drawings:  <input type="checkbox"/> received:  <input type="checkbox"/> not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:	
4. Date of timely receipt of the required corrections under PCT Article 11(2):	
5. International Searching Authority (if two or more are competent): ISA / JP	
6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid.	

For International Bureau use only
Date of receipt of the record copy by the International Bureau:

E P



P C T

国際調査報告

(法 8 条、法施行規則第40、41条)  
〔PCT 18 条、PCT 規則43、44〕

出願人又は代理人 の書類記号 1192	今後の手続きについては、国際調査報告の送付通知様式(PCT/ISA/220)及び下記5を参照すること。	
国際出願番号 PCT/JP00/01070	国際出願日 (日.月.年) 24.02.00	優先日 (日.月.年) 25.02.99
出願人 (氏名又は名称) 協和醗酵工業株式会社		

国際調査機関が作成したこの国際調査報告を法施行規則第41条 (PCT 18 条) の規定に従い出願人に送付する。  
この写しは国際事務局にも送付される。

この国際調査報告は、全部で 3 ページである。

☐ この調査報告に引用された先行技術文献の写しも添付されている。

#### 1. 国際調査報告の基礎

a. 言語は、下記に示す場合を除くほか、この国際出願がされたものに基づき国際調査を行った。

☐ この国際調査機関に提出された国際出願の翻訳文に基づき国際調査を行った。

b. この国際出願は、ヌクレオチド又はアミノ酸配列を含んでおり、次の配列表に基づき国際調査を行った。

☐ この国際出願に含まれる書面による配列表

☒ この国際出願と共に提出されたフレキシブルディスクによる配列表

☐ 出願後に、この国際調査機関に提出された書面による配列表

☐ 出願後に、この国際調査機関に提出されたフレキシブルディスクによる配列表

☐ 出願後に提出した書面による配列表が出願時における国際出願の開示の範囲を超える事項を含まない旨の陳述書の提出があった。

☒ 書面による配列表に記載した配列とフレキシブルディスクによる配列表に記載した配列が同一である旨の陳述書の提出があった。

2. ☐ 請求の範囲の一部の調査ができない (第 I 欄参照)。

3. ☐ 発明の単一性が欠如している (第 II 欄参照)。

4. 発明の名称は ☒ 出願人が提出したものを承認する。

☐ 次に示すように国際調査機関が作成した。

5. 要約は ☒ 出願人が提出したものを承認する。

☐ 第 III 欄に示されているように、法施行規則第47条 (PCT 規則38.2(b)) の規定により国際調査機関が作成した。出願人は、この国際調査報告の発送の日から 1 カ月以内にこの国際調査機関に意見を提出することができる。

6. 要約書とともに公表される図は、

第 \_\_\_\_\_ 図とする。 ☐ 出願人が示したとおりである。

☒ なし

☐ 出願人は図を示さなかった。

☐ 本図は発明の特徴を一層よく表している。

## A. 発明の属する分野の分類 (国際特許分類 (IPC))

Int Cl<sup>7</sup> C12N15/54, C12P21/02, C12N9/10, C12N1/21, C12N5/14, C12N5/16, C12Q1/68, C12N15/63, A01K67/027, G01N33/15, G01N33/50, G01N33/574, A01H5/00

## B. 調査を行った分野

調査を行った最小限資料 (国際特許分類 (IPC))

Int Cl<sup>7</sup> C12N15/54, C12P21/02, C12N9/10, C12N1/21, C12N5/14, C12N5/16, C12Q1/68, C12N15/63, A01K67/027, G01N33/15, G01N33/50, G01N33/574, A01H5/00

最小限資料以外の資料で調査を行った分野に含まれるもの

国際調査で使用した電子データベース (データベースの名称、調査に使用した用語)

Genbank/EMBL/DDBJ/GeneSeq, WPI(DIALOG), BIOSIS (DIALOG)

## C. 関連すると認められる文献

引用文献の カテゴリー*	引用文献名 及び一部の箇所が関連するときは、その関連する箇所の表示	関連する 請求の範囲の番号
P, X	ZHOU, D. et al, "Molecular cloning of a human UDP-galactose: GlcNAc $\beta$ 1,3GalNAc $\beta$ 1,3 galactosyltransferase gene encoding an O-linked core3-elongation enzyme", Eur. J. Biochem., (July, 1999) Vol. 263, No. 2 p. 571-576	1-47
P, X	ISSHIKI, S. et al, "Cloning, expression, and characterization of a novel UDP-galactose: $\beta$ -N-acetylglucosamine $\beta$ 1,3-galactosyltransferase ( $\beta$ 3Gal-T5) responsible for synthesis of type 1 chain in colorectal and pancreatic epithelia and tumor cells derived therefrom",	1-47

☒ C欄の続きにも文献が列举されている。

☐ パテントファミリーに関する別紙を参照。

## \* 引用文献のカテゴリー

- 「A」 特に関連のある文献ではなく、一般的技術水準を示すもの  
「E」 国際出願日前の出願または特許であるが、国際出願日以後に公表されたもの  
「L」 優先権主張に疑義を提起する文献又は他の文献の発行日若しくは他の特別な理由を確立するために引用する文献 (理由を付す)  
「O」 口頭による開示、使用、展示等に言及する文献  
「P」 国際出願日前で、かつ優先権の主張の基礎となる出願

の日の後に公表された文献

- 「T」 国際出願日又は優先日後に公表された文献であって出願と矛盾するものではなく、発明の原理又は理論の理解のために引用するもの  
「X」 特に関連のある文献であって、当該文献のみで発明の新規性又は進歩性がないと考えられるもの  
「Y」 特に関連のある文献であって、当該文献と他の1以上の文献との、当業者にとって自明である組合せによって進歩性がないと考えられるもの  
「&」 同一パテントファミリー文献

国際調査を完了した日

23. 05. 00

国際調査報告の発送日

30.05.00

国際調査機関の名称及びあて先

日本国特許庁 (ISA/J P)

郵便番号 100-8915

東京都千代田区霞が関三丁目4番3号

特許庁審査官 (権限のある職員)

六笠 紀子

4 B

9 7 3 5

電話番号 03-3581-1101 内線 3448

## C (続き) . 関連すると認められる文献

引用文献の カテゴリー*	引用文献名 及び一部の箇所が関連するときは、その関連する箇所の表示	関連する 請求の範囲の番号
	J. Biol. Chem. , (April, 1999) Vol. 274, No. 18 p. 12499-12507	
P, X	BARDONI, A. et al, "Differential expression of $\beta$ 1,3 galactosyltransferases in human colon cells derived from adenocarcinomas or normal mucosa", FEBS Letters, (May, 1999) Vol. 451, No. 1, p. 75-80	1-47
P, X	JP, 11-56373, A (古川鋼一) 2. 3月. 1999 (02. 03. 99) パテントファミリー無し	1-47
X	ZHOU, D. et al, "A $\beta$ -1,3-N-acetylglucosaminyltransferase with poly-N-acetyllactosamine synthase activity is structurally related to $\beta$ -1,3- galactosyltransferases", Proc. Natl. Acad. Sci. USA. , (Jan. , 1999) Vol. 96, No. 2 p. 406-411	1-47
X	AMADO, M. et al, "A family of human $\beta$ 3-galactosyltransferases", J. Biol. Chem. , (1998) Vol. 273, No. 21, p. 12770-12778	1-47
X	HENNET, T. et al, "Genomic cloning and expression of three murine UDP-galactose: $\beta$ -N-acetylglucosamine $\beta$ 1,3-galactosyltransferase genes", J. Biol. Chem. , (1998) Vol. 273, No. 1, p. 58-65	1-47
X	JP, 6-181759, A (協和醗酵工業株式会社) 5. 7月. 1994 (05. 07. 94) パテントファミリー無し	1-47